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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,077

09/27/2004

Christopher Norbert Johnson

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05/18/2006

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EXAMINER

BERNHARDT, EMILY B

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/509,077

Applicant(s)

JOHNSON ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

The BIB data sheet lists 4 foreign priority documents followed by a “NO” for each entry. Applicants should request a corrected filing receipt. Additionally, a review of these documents and the oath show that British application # 0207278.3 is not mentioned in the oath for 119 priority. Is this correct?

The abstract of the disclosure is objected to because a formula should be depicted showing overall structural makeup. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:
Throughout the pages of the spec there are many instances of illegible text beginning on p.1. Substitute pages are needed.

Appropriate correction is required.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In defining X/Y choices in main claim 1 it is stated that at least one of them must be =N and the other one $-N(R^5)-$ yet it is not seen how X can be anything other than =N since its always doubly bonded and Y can only be $-N(R^5)-$.

Clarification of the claim language is thus needed.

2. Claim 2 is incomplete as recited since it does not particularly point out the invention by naming species so that one reading the claims can ascertain its scope but rather resorts to examples in the specification which is improper. Note reliance on the specification to define claimed subject matter is permitted only under certain circumstances as discussed in *Ex parte Fressola* 27 USPQ 2d 1608.

Claims 1,3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following reasons apply.

1. Scope of solvates is not adequately enabled. The only one mentioned is hydrate formation. Claims which embrace any solvate are nonenabled since generally not all solvents can form solvates with all compounds. There is no process enabling such a scope in the specification .

2. Starting material sources for the bicyclic rings resulting from one of R1 joining with R2 and spiro fusion permitted at R2 are not seen but are required.

Specification is silent as to the availability of necessary reactants needed to prepare such ring systems of if they are commercially available. Note *In re Howarth* 210 USPQ 689; *Ex parte Moersch* 104 USPQ 122 for the need to show starting

material sources commensurate with the claims' scope.

2.As there are no such other bicyclic and spirofused compounds that have been made corresponding to the instant scope which include ortho-fused and bridged compounds for the former, there is no reasonable basis for assuming that the myriad of compounds embraced by all the generic claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. The same applies for the scope of hetero rings permitted in "A" which includes heteroaryls which can be monocyclic, bicyclic and further substituted with more groups as well rings formed at NR6R7 and/or NR8R9 of varying degrees of unsaturation and size. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art.

Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition, which includes factors such as:

1) Breadth of the claims- the claims cover compounds easily in the millions as pointed out above;

2) Level of unpredictability in the art- the invention is pharmaceutical in nature as it involves binding to serotonin (5HT-6) receptors. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved” and physiological activity is generally considered to be unpredictable. See *In re Fisher* 166 USPQ 18;

3) Direction or guidance- compounds made are not representative of the instant scope but are closer to each other than to remaining scope being always piperazine with A ring aryl;

4) State of the prior art- The compounds are piperazine derivatives with fused rings at one end which are substituted with arylsulfonyls and heteroaryl sulfonyls. While such compounds are known as evident from the art applied below, they are similar in structure to the compounds made herein and thus do not evidence the many structural permutations permitted in the instant scope are known for at least one use in the prior art;

5) Working examples- While test data has been presented for prepared compounds only a lower range has been reported and compounds are similar at “A” and thus no clear evaluation of what other rings present as A and at other positions might affect potency to a large or small degree.

In view of the above considerations, this rejection is being applied.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernotas (US'030 A1). The US publication describes very similar compounds as 5-HT₆ antagonists. See formula (I), especially definition of R₄-R₇ which includes the piperazine ring. Species on p.5 namely [0073], [0075], [0086] differ only in being position isomers- i.e. attachment of piperazine ring is at 5 or 6 position of the pyrrolo[3,2-b]pyridine vs. instant 7-position. Note that Bernotas permits the piperazine to float on all available ring positions of the pyridine ring as can be seen in the R₄-R₇ definitions. Position isomers are not deemed patentably distinct absent evidence of superior, unexpected results. See *In re Crounse* 150 USPQ 554; *Ex parte Engelhardt* 208 USPQ 343 regarding position isomerism. Thus it would have been obvious to one skilled in the art at the time the invention was made to expect instant 7-piperazine derivatives to also possess the uses taught by the applied art in view of the close structural similarity as well as equivalency teaching outlined above.

Bernotas is applied as of its US provisional filing date which precedes applicants' international filing date since relevant subject matter is also described therein. While applicants are claiming 119 benefit for at least 3 of the 4 listed documents in the Bib data sheet, **no one** document describes all of the subject matter being claimed in any **one** claim. For 119 benefit a claimed invention must be described in a **single** earlier-filed application as set forth in Yamada v.

Aggarwal 57 USPQ2d 2002.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansson (US'210 A1). The US publication describes similar quinoline compounds . See species [0255]-[0269] which differ as being position isomers as the attachment of the piperazine ring in Johansson is other than the 8-position required in formula (iv). The same remarks made in Bernotas regarding position isomers also applies herein. Note that Johansson teaches that the piperazine ring (in the R3 definition) can be present on any location on carbon of the A or B ring. See p.3, section [0036]. Thus it would have been obvious to one skilled in the art at the time the invention was made to expect instant 8-piperazine quinolinyl derivatives to also possess the uses taught by the applied art in view of the close structural similarity as well as equivalency teaching outlined above.

Johansson is being applied as of its earliest provisional case of 8/26/02 since

quinolines are taught at least in part therein. 119 benefit is not being accorded applicants for the reason set forth above.

Applicants' IDS filed 9/27/04 is noted but no references are seen in the file. Once received they will be considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Emily Bernhardt
Primary Examiner
Art Unit 1624